STATEMENT OF EMERGENCY

907 KAR 1:018E

(1) This emergency administrative regulation is being promulgated to enable the Department for Medicaid Services (DMS) to establish a state maximum allowable cost for any drug for which two (2) or more multi-source drugs with a significant cost difference exist; to alter drug reimbursement to AWP minus fourteen (14) percent for generic drugs and AWP minus fifteen (15) percent for brand name drugs; to alter the dispensing fee from four (4) dollars and fifty-one (51) cents for all drugs to five (5) dollars for generic drugs and four (4) dollars and fifty (50) cents for brand name drugs; to revise the unit dose drug packaging payment to $0.02 per unit dose for a non-unit dose drug repackaged in unit dose form by a pharmacist; to allow one dispensing fee per rolling twenty-four (24) day period per nursing facility service recipient per drug except for certain circumstances; to establish for an outpatient service recipient, excluding supports for community living service recipients, that a maintenance drug shall be dispensed up to a ninety-two (92) day supply with only one (1) dispensing fee allowed for the maintenance drug refill within the ninety-two (92) day time period; to establish that if the dispensing of an emergency supply of a drug results in partial filling of the quantity or amount prescribed, that only one dispensing fee shall be allowed for the combined partial fill and subsequent completion fill; and to add gross amount due to drug reimbursement options. This action must be taken on an emergency basis to ensure the viability of the Medicaid program and to best utilize the program's resources in serving the health, safety and welfare needs of Medicaid recipients.

(2) Failure to enact this administrative regulation on an emergency basis would pose an imminent threat to the public health, safety or welfare of Medicaid recipients whose receipt of services may be jeopardized due to a lack of funding or provider accessibility.

(3) This emergency administrative regulation differs from the emergency administrative regulation filed with the Legislative Research Commission on January 28, 2005 in that it alters drug reimbursement to AWP minus fourteen (14) percent for a generic drug and AWP minus fifteen (15) percent for a brand name drug and in that it alters the dispensing fee from four (4) dollars and fifty-one (51) cents for all drugs to five (5) dollars for generic drugs and four (4) dollars and fifty (50) cents for brand name drugs; and in that it allows up to four (4) dispensing fees within a rolling twenty-four (24) day period for legend intravenous drugs.

(4) This emergency administrative regulation shall be replaced by an ordinary administrative regulation filed with the Regulations Compiler.

_____
Ernie Fletcher
Governor

_____
James W. Holsinger, Jr., M.D., Secretary
Cabinet for Health and Family Services

CABINET FOR HEALTH AND FAMILY SERVICES

Department for Medicaid Services

Office of the Commissioner

(Emergency Amendment)

907 KAR 1:018E. Reimbursement for drugs.

RELATES TO: KRS 205.560, 205.561, 205.5631, 205.5632, 205.5634, 205.5636, 205.5638, 205.5639, 205.6316(4), 217.015, 311.550, 311.560, 42 C.F.R. 440.120, 447.331, 447.332, 447.333, 42 U.S.C. 256b, 1396a-d

STATUTORY AUTHORITY: KRS 194A.030(3), 194A.050(1), 205.520(3), 205.560, 205.561(4), 205.6316(4), EO 2004-726

NECESSITY, FUNCTION, AND CONFORMITY: Executive Order 2004-726, effective July 9, 2004, reorganized the Cabinet for Health Services and placed the Department for Medicaid Services and the Medicaid Program under the Cabinet for Health and Family Services. The Cabinet for Health and Family Services, Department for Medicaid Services has responsibility to administer the Medicaid Program. KRS 205.520(3) authorizes the cabinet, by administrative regulation, to comply with any requirement that may be imposed, or opportunity presented, by federal law for the provision of medical assistance to Kentucky's indigent citizenry. KRS 205.6316(4) requires the department to promulgate an administrative regulation to establish a dispensing fee for prescriptions. This administrative regulation establishes the method for determining reimbursement for drugs through the Medicaid Outpatient Pharmacy Program and the dispensing fees.

Section 1. Definitions. (1) "A-rated generic product" means a product that the FDA has found to be bioequivalent.

(2) "Average wholesale price" or "AWP" means the average wholesale price published in a nationally recognized comprehensive drug data file for which the department has contracted.

(3) "Department" means the Department for Medicaid Services or its designated agent.

(4) "Direct price" means the estimated acquisition cost for which a retailer can purchase a drug product directly from the manufacturer as listed in a nationally-recognized comprehensive drug data file for which the department has contracted.

(5) "Dispensing fee" means a professional fee paid to reimburse a pharmacy for costs associated with the dispensing of a prescribed drug.

(6) "Food and Drug Administration" or "FDA" means the Food and Drug Administration of the United States Department of Health and Human Services.

(7) “Gross amount due” means the total price of a drug claimed from all sources, which includes the ingredient cost paid and which may include the dispensing fee paid and or the incentive amount paid. [~~"Nonsolid dosage form" means a covered drug item other than an oral tablet, oral capsule, or inhaler.~~]

(8) "Wholesale acquisition cost" or "WAC" means the estimated acquisition cost for the wholesaler as listed in a nationally-recognized comprehensive drug data file for which the department has contracted.

Section 2. Reimbursement (1) [~~Except as specified in subsection (4)(e) of this section, reimbursement to a participating provider shall be comprised of a dispensing fee~~

~~and the cost of the drug product.~~] If a recipient is required to pay a copayment for a drug in accordance with 907 KAR 1:604, the reimbursement to the participating provider [~~for the dispensing fee~~] shall be reduced by one (1) dollar [~~the amount of the copayment~~].

(2) The department: [~~shall:~~]

(a) May establish a state maximum-allowable cost for a drug:

1. If two (2) or more A-rated therapeutically equivalent, multi-source, non-innovator drugs with a significant cost difference exist for the given drug; and

2. By reviewing the pricing sources AWP, WAC, and direct price for the drug as identified in a nationally-recognized comprehensive drug data file for which the department has contracted and utilizing the weighted majority of volume purchased; and

(b) Shall maintain a current listing of drugs and their corresponding state maximum allowable costs via a link from the department web site located at the following address: http://www.chfs.ky.gov/dms.

(3) An appeal of a state maximum allowable cost price for a drug shall be as follows:

(a)1. The provider shall email or fax a completed "MAC Price Inquiries and Research Request Form" (which is available at the department and at the website address http://kentucky.fhsc.com/providers/documents.asp by clicking on "MAC Price Inquiries and Research Request Form or via the specific website address http://kentucky.fhsc.com/Downloads/providers/KYRx_MACResearchRequestForm.pdf) to First Health Services Corporation. The email address is rebate@fhsc.com and the fax number is 804-217-7911; or

2. The provider shall contact the First Health Services Corporation technical call center at 1-800-432-7005 and provide information regarding the appeal including the

national drug code for the drug in question;

(b) An appeal of a state maximum allowable cost price for a drug shall be investigated and resolved within three (3) business days;

(c) If available, the provider shall be supplied with the name of one (1) or more manufacturers who have a price comparable to the state maximum allowable cost price;

(d) The state maximum allowable cost price and effective date of that price shall be adjusted accordingly, retroactive to the date of service for the state maximum allowable cost price prescription in question, if:

1. It is determined that no manufacturer exists in the price range referenced in subsection (3)(c) of this section; or

2. The provider is able to document that despite reasonable efforts to obtain access, he or she does not have access to the one (1) or more manufacturers supplied to the provider; and

(e) When the change in state maximum allowable cost price for a price that is adjusted becomes effective, the provider shall be informed that the claim may be re-billed for the price adjustment.

~~[1. For which a federal upper limit does not exist; and~~

~~2. For which at least one (1) readily and nationally-available A-rated generic product exists;~~

~~(b) Determine a state maximum allowable cost for a drug by identifying the lowest price for a drug regardless of manufacturer, including both generic and brand name, and multiplying that price by 150 percent. The lowest price for a drug shall be:~~

~~1. Identified in a nationally-recognized comprehensive drug data file for which the~~

~~the department has contracted; and~~

~~2. Determined by reviewing the pricing sources determinations of AWP, WAC, and direct price for the drug;~~

~~(c) Remove a state maximum allowable cost for a drug if a federal upper limit becomes available for the drug; and~~

~~(d) Maintain a current listing of drugs and their corresponding state maximum allowable costs at the department website located at the following address: http://chs.ky.gov/dms.~~

~~(3) A provider may submit drug acquisition cost or product availability information to the department. Upon receipt of accurate documentation (including recent drug purchase summaries, invoices, or remittance advices) from the provider, the department:~~

~~(a) Shall review the referenced product and its corresponding state maximum-allowable cost value to ensure it reflects an accurate market price and availability; and~~

~~(b) May consider adjusting or removing the state maximum-allowable cost for the drug if the department determines that the state maximum-allowable cost does not accurately reflect current market price or conditions.~~]

(4) Reimbursement to a pharmacy participating in the Medicaid Program for a drug listed in the Kentucky Medicaid Outpatient Drug List [~~Formulary~~] established in 907 KAR 1:019 and provided to an eligible recipient shall be determined in accordance with the requirements established in this subsection.

(a) An appropriate rebate agreement shall be signed by the drug manufacturer or the drug shall be provided based on a prior authorized exemption from the rebate requirement in accordance with 907 KAR 1:019.

(b) Drug costs shall be determined in the Pharmacy Program using drug pricing and coding information obtained from a nationally-recognized comprehensive drug data file for which the department has contracted with pricing based on the actual package size utilized.

(c) Reimbursement for a drug shall be the lesser of:

1. The federal upper limit, if one (1) exists, plus a dispensing fee and, if applicable, a unit dose addition;

2. The state maximum allowable cost, if one (1) exists, plus a dispensing fee and, if applicable, a unit dose addition;

3. The estimated acquisition cost (EAC) which shall:

a. For a generic drug equal the AWP minus fourteen (14) percent, plus a dispensing fee and, if applicable, a unit dose addition; and

b. For a brand name drug equal the AWP minus fifteen (15) percent, plus a dispensing fee and, if applicable, a unit dose addition;

4. The usual and customary billed charge; or

5. The gross amount due.

(d) Reimbursement for the dispensing of an emergency supply of a drug shall be:

1. Made only outside normal business hours of the department's drug prior authorization office and as permitted in accordance with 907 KAR 1:019, Section 4; and

2. The lesser of:

a. The federal upper limit, if one (1) exists, plus the dispensing fee for the prescription and, if applicable, a unit dose addition;

b. The state maximum allowable cost, if one (1) exists, plus a dispensing fee and, if

applicable, a unit dose addition;

c. The estimated acquisition cost (EAC), which shall:

(i) For a generic drug, equal the AWP minus fourteen (14) percent, plus a dispensing fee and, if applicable, a unit dose addition; and

(ii) For a brand name drug, equal the AWP minus fifteen (15) percent, plus a dispensing fee and, if applicable, a unit dose addition;

d. The usual and customary billed charge; or

e. The gross amount due. [~~Except as provided in paragraphs (d) and (e) of this subsection, reimbursement for a drug shall be the lesser of:~~

~~1. The federal upper limit plus a dispensing fee and unit dose add-on as appropriate;~~

~~2. The state maximum allowable cost plus a dispensing fee and unit dose add-on as appropriate if a federal upper limit is unavailable~~;

~~3. The estimated acquisition cost (EAC) which shall equal the AWP minus twelve (12) percent, plus a dispensing fee and unit dose add-on as appropriate; or~~

~~4. The usual and customary billed charge.~~

~~(d) Except as provided in paragraph (e) of this subsection, if a prescriber has met the requirements specified in 907 KAR 1:019 for obtaining a brand name drug for which one (1) or more generic forms of the drug are available and has hand written "brand medically necessary" or "brand necessary" on the Brand Name Drug Request Form or other form in accordance with 907 KAR 1:019, the reimbursement shall be the lesser of:~~

~~1. The estimated acquisition cost (EAC) which shall equal the AWP minus twelve (12) percent, plus a dispensing fee and unit dose add-on as appropriate; or~~

~~2. The usual and customary billed charge.~~

~~(e) 1. Reimbursement for the dispensing of an emergency supply of a drug shall be made only outside normal business hours of the department's drug prior authorization office and as permitted in accordance with 907 KAR 1:019, Section 4.~~

~~2. Except as specified in subparagraph 3 of this paragraph, reimbursement for the dispensing of an emergency supply of a drug shall be the lesser of:~~

~~a. The federal upper limit plus the dispensing fee for the prescription and, if applicable, a unit dose add-on;~~

~~b. The state maximum allowable cost plus a dispensing fee and unit dose add-on as appropriate;~~

~~c. The estimated acquisition cost (EAC), which shall equal the average wholesale price (AWP) minus twelve (12) percent, plus the dispensing fee for the prescription and, if applicable, a unit dose add-on; or~~

~~d. The usual and customary billed charge.~~

~~3. If a prescriber has met the requirements specified in 907 KAR 1:019 for obtaining a brand name drug for which one (1) or more generic forms of the drug are available and has hand written "brand medically necessary" or "brand necessary" on the Brand Name Drug Request Form or other form in accordance with 907 KAR 1:019, the reimbursement for the dispensing of an emergency supply of a drug shall be the lesser of:~~

~~a. The estimated acquisition cost (EAC), which shall equal the average wholesale price (AWP) minus twelve (12) percent, plus the dispensing fee for the prescription and, if applicable, a unit dose add-on; or~~

~~b. The usual and customary billed charge.~~]

(e) [4.] If the dispensing of an emergency supply results in partial filling of the quantity or amount prescribed, reimbursement for the partial filling of the remainder of the prescription shall utilize the methodology specified in subparagraphs 2 and 3 of this paragraph, except that only one dispensing fee shall be allowed for the combined partial fill and subsequent completion fill [~~reimbursement shall not include a dispensing fee~~].

(f) Reimbursement shall be denied if:

1. The recipient is ineligible on the date of service;

2. The drug is excluded from coverage in accordance with 907 KAR 1:019, Section 3; or

3. Prior authorization is required by the department and has been denied or has not been requested.

(g) For a nursing facility resident meeting Medicaid nursing facility level of care criteria in accordance with 907 KAR 1:022, there shall not be more than one dispensing fee allowed per provider per recipient per drug within a rolling twenty-four (24) day period unless:

1. The drug is a Schedule II, III, or IV controlled substance or a legend intravenous drug, in which case up to three (3) additional dispensing fees shall be allowed;

2. The drug is a non-solid dosage form, in which case one (1) additional dispensing fee shall be allowed;

3. The prescribed dosage has been changed, in which case one (1) additional dispensing fee shall be allowed; or

4. The department determines that it is in the best interest of the recipient to allow the additional dispensing fee. [~~:~~

~~1. One (1) dispensing fee allowed per drug within a calendar month for a drug classified by the Medicaid program as a maintenance drug unless the prescribed dosage has been changed;~~

~~2. Except as specified in subparagraphs 1 and 3 of this paragraph, two (2) dispensing fees allowed per drug within a calendar month for other drugs; and~~

~~3. Four (4) dispensing fees per drug within a calendar month for a nonsolid dosage form a Schedule II, III or IV controlled substance or a legend intravenous drug.~~]

(h) For a nursing facility resident meeting Medicaid nursing facility level of care criteria and if appropriate and in accordance with 201 KAR 2:190 and 902 KAR 55:065, an unused drug, paid for by Medicaid, shall be returned to the originating pharmacy and the department shall be credited for the cost of the drug and the unit dose packaging cost.

(i)1. A maintenance drug shall be dispensed to an outpatient service recipient, except for an individual receiving supports for community living services, up to a ninety-two (92) day supply with only one (1) initial dispensing fee and one (1) refill dispensing fee allowed within the ninety-two (92) day time period unless the department determines that it is in the best interest of the recipient to allow any additional dispensations or dispensing fees; and

2. For an outpatient service [~~or personal care~~] recipient receiving services via the supports for community living program there shall not be more than:

a. [~~1.~~] One (1) dispensing fee allowed per drug per calendar month for a drug classified by the Medicaid Program as a maintenance drug unless there is an exception described in subparagraph 3 of this paragraph;

b. [~~2.~~] Four (4) dispensing fees allowed per drug within a calendar month for a legend intravenous drug or a Schedule II, III or IV controlled substance; or

c.(i) [~~3.a.~~] Two (2) dispensing fees allowed per drug within a six (6) month period for a refill of a maintenance prescription requested less than twenty-three (23) days from the last date the medication was dispensed; or

(ii) [~~b.~~] Four (4) dispensing fees allowed per maintenance drug in one (1) month if a prescriber requests to prescribe less than a thirty (30) day supply based on medical specialty, best practice standards, and appropriateness of care.

(j) For a personal care recipient there shall not be more than:

1. One (1) dispensing fee allowed per drug per calendar month for a drug classified by the Medicaid Program as a maintenance drug unless there is an exception described in subparagraph 3 of this paragraph;

2. Four (4) dispensing fees allowed per drug within a calendar month for a legend intravenous drug or a Schedule II, III or IV controlled substance; or

3.a. Two (2) dispensing fees allowed per drug within a six (6) month period for a refill of a maintenance prescription requested less than twenty-three (23) days from the last date the medication was dispensed; or

b. Four (4) dispensing fees allowed per maintenance drug in one (1) month if a prescriber requests to prescribe less than a thirty (30) day supply based on medical specialty, best practice standards, and appropriateness of care.

(k) [~~(j)~~] Reimbursement shall not be made for more than one (1) prescription to the same recipient on the same day for a drug with the same:

1. National Drug Code (NDC); or

2. Generic name, strength, and dosage form.

(5) For a Medicaid recipient participating in a hospice program, payment for a drug shall be in accordance with 907 KAR 1:340.

(6) A pharmacy claim shall meet the point of sale (POS) requirements for services in accordance with 907 KAR 1:673.

(7) If a payment is made for a drug for which there is no authorization as required in accordance with 907 KAR 1:019, the provider shall reimburse the department the amount of the payment.

(8) A timely claim payment shall be processed in accordance with 42 C.F.R. 447.45.

(9) A claim in which retroactive eligibility is established shall be submitted up to twelve (12) months from the issue date noted on the Medicaid recipient's medical assistance identification card. If the date of service is greater than twelve (12) months old, the claim shall be submitted as a paper claim with a copy of the retroactive medical assistance identification card attached.

(10) Pursuant to KRS 205.622, prior to billing the department, a provider shall submit a bill to Medicare if the provider has knowledge that Medicare may be liable for payment.

(11)(a) If the medical assistance identification card indicates that the Medicaid recipient has additional insurance, the provider shall submit a bill to the third party in accordance with KRS 205.622.

(b) A provider who is aware that a recipient has other insurance, but no insurance is indicated on the medical assistance identification card, shall submit a Third-party Liability Lead Form to the department's fiscal agent.

(12) Adherence to the requirements established in this section shall be monitored through an on-site audit, postpayment review of the claim, a computer audit or an edit of the claim.

(13)(a) A pharmacy of a covered entity as defined in 42 U.S.C. 256b which purchases drugs through the United States Public Health Service Discount Program in accordance with 42 U.S.C. 256b shall bill the department the pharmacy's actual acquisition cost for a drug; and

(b) The department shall reimburse the pharmacy's actual acquisition cost for the drug plus a dispensing fee in accordance with Section 3 of this administrative regulation.

(14) If a covered entity as defined in 42 U.S.C. 256b notifies the United States Office of Pharmacy Affairs that its pharmacy is not included under 42 U.S.C. 256b:

(a) The pharmacy shall submit [~~bill~~] its usual and customary amount and gross amount due for a drug; and

(b) The department shall reimburse for a drug in accordance with Section 2 of this administrative regulation plus a dispensing fee in accordance with Section 3 of this administrative regulation.

Section 3. Dispensing Fees. (1) To determine a dispensing fee, the department shall comply with KRS 205.561.

(2) Except as provided in subsection (3) of this section and in accordance with KRS

205.561, [~~, based on the conclusion of the dispensing fee study of the report conducted in accordance with KRS 205.561~~,] the dispensing fee, unless excluded by Section 2(4)(e) of this administrative regulation, shall be:

(a) Five (5) dollars [~~four (4) dollars and fifty-one (51) cents~~] per prescription for a generic drug reimbursed through the outpatient drug program if dispensed to an eligible recipient, including an eligible recipient in a nursing facility meeting the nursing facility level of care criteria requirements established in 907 KAR 1:022; and

(b) Four (4) dollars and fifty (50) cents per prescription for a brand name drug reimbursed through the outpatient drug program if dispensed to an eligible recipient, including an eligible recipient in a nursing facility meeting the nursing facility level of care criteria requirements established in 907 KAR 1:022.

(3)(a) For a recipient in a nursing facility meeting the nursing facility level of care criteria requirements established in 907 KAR 1:022, a unit dose addition to the usual reimbursement shall be made for a drug dispensed through the Pharmacy Outpatient Drug Program in the amount of two (2) cents per unit dose for a non-unit dose drug repackaged in unit dose form by the pharmacist. [~~:~~

~~1.Two (2) cents per unit dose for a unit dose drug packaged in unit dose form by the manufacturer; and~~

~~2. Four (4) cents per unit dose for a unit dose drug packaged in unit dose form by the pharmacist.~~]

(b) The unit dose addition shall be paid, as appropriate, even though the usual dispensing fee of five (5) dollars for a generic drug or four (4) dollars and fifty (50) cents for a brand name drug [~~four (4) dollars and fifty-one (51) cents~~] is not paid due to

monthly limits on dispensing fees or in accordance with Section 2(4)(e) of this administrative regulation.

Section 4. Reimbursement to Dispensing Physicians. A participating dispensing physician who practices in a county where a pharmacy is not located shall be reimbursed for the cost of the drug, with the cost computed:

(1) As the lesser of:

(a) The maximum allowable cost or estimated acquisition cost established in Section 2(4) of this administrative regulation; [~~or~~]

(b) The physician's usual and customary amount or gross amount due; or [~~charge to the general public for the drug; or~~]

(c) The federal upper limit.

(2) In accordance with 907 KAR 3:010 for a free immunization through the Vaccines for Children Program.

Section 5. Material Incorporated by Reference. The "MAC Price Inquiries and Research Request Form, December 2004 edition", is incorporated by reference and may be inspected, copied, or obtained, subject to applicable copyright law, at the Department for Medicaid Services, 275 East Main Street, Frankfort, Kentucky 40621, Monday through Friday, 8 a.m. to 4:30 p.m.

907 KAR 1:018E

REVIEWED:

Date	Shannon Turner, J.D., Commissioner Department for Medicaid Services
Date	Duane L. Kilty Jr., Ph.D Undersecretary for Administration and Fiscal Affairs

APPROVED:

Date	James. W. Holsinger, Jr., M.D., Secretary Cabinet for Health and Family Services

REGULATORY IMPACT ANALYSIS
AND TIERING STATEMENT

Administrative Regulation #: 907 KAR 1:018E
Cabinet for Health and Family Services
Department for Medicaid Services
Agency Contact Person: Stuart Owen or Stephanie Brammer-Barnes (564-6204)

(1) Provide a brief summary of:
(a) What this administrative regulation does: This administrative regulation establishes the method for determining reimbursement for drugs through the Medicaid outpatient pharmacy program.
(b) The necessity of this administrative regulation: This administrative regulation is necessary to establish the method for determining reimbursement for drugs through the Medicaid outpatient pharmacy program.
(c) How this administrative regulation conforms to the content of the authorizing statutes: This administrative regulation conforms to the content of the authorizing statutes by establishing the method for determining reimbursement for drugs through the Medicaid outpatient pharmacy program.
(d) How this administrative regulation currently assists or will assist in the effective administration of the statutes: This administrative regulation currently assists and will continue to assist in the effective administration of the authorizing statutes by establishing the method for determining reimbursement for drugs through the Medicaid outpatient pharmacy program.

(2) If this is an amendment to an existing administrative regulation, provide a brief summary of:
(a) How the amendment will change this existing administrative regulation: The amendment to this administrative regulation includes establishing a state maximum allowable cost for any drug for which two (2) or more multi-source drugs with a significant cost difference exist; altering drug reimbursement to AWP minus fourteen (14) percent for generic drugs and AWP minus fifteen (15) percent for brand name drugs; altering the dispensing fee from four (4) dollars and fifty-one (51) cents for all drugs to five (5) dollars for generic drugs and four (4) dollars and fifty (50) cents for brand name drugs; revising the unit dose drug packaging payment to $0.02 per unit dose for a non-unit dose drug re-packaged in unit dose form by a pharmacist; allowing one dispensing fee per rolling twenty-four (24) day period per nursing facility service recipient per drug except for certain circumstances; establishing for an outpatient service recipient, except for a supports for community living service recipient, that a maintenance drug shall be dispensed up to a ninety-two (92) day supply with only one (1) dispensing fee allowed for the maintenance drug refill within the ninety-two (92) day time period; establishing that if the dispensing of an emergency supply of a drug results in partial filling of the quantity or amount prescribed, that only one dispensing fee shall be allowed for the combined

partial fill and subsequent completion fill; and adding gross amount due to drug reimbursement options.

(b) The necessity of the amendment to this administrative regulation: The amendment to this administrative regulation is necessary to control rising pharmacy reimbursement costs in the Medicaid program in order to maintain the financial viability of the Department for Medicaid Services. This amendment would bring Medicaid more in line with other state Medicaid plans as well as the commercial sector.

(c) How the amendment conforms to the content of the authorizing statutes: The amendment to this administrative regulation conforms to the content of the authorizing statutes by establishing a state maximum allowable cost for any drug for which two (2) or more multi-source drugs with a significant cost difference exist; altering drug reimbursement to AWP minus fourteen (14) percent for generic drugs and AWP minus fifteen (15) percent for brand name drugs; altering the dispensing fee from four (4) dollars and fifty-one (51) cents for all drugs to five (5) dollars for generic drugs and four (4) dollars and fifty (50) cents for brand name drugs; revising the unit dose drug packaging payment to $0.02 per unit dose for a non-unit dose drug re-packaged in unit dose form by a pharmacist; allowing one dispensing fee per rolling twenty-four (24) day period per nursing facility service recipient per drug except for certain circumstances; establishing for an outpatient service recipient, except for a supports for community living service recipient, that a maintenance drug shall be dispensed up to a ninety-two (92) day supply with only one (1) dispensing fee allowed for the maintenance drug refill within the ninety-two (92) day time period; establishing that if the dispensing of an emergency supply of a drug results in partial filling of the quantity or amount prescribed, that only one dispensing fee shall be allowed for the combined partial fill and subsequent completion fill; and adding gross amount due to drug reimbursement options.

(d) How the amendment will assist in the effective administration of the statutes: The amendment to this administrative regulation will assist in the effective administration of the authorizing statutes by establishing a state maximum allowable cost for any drug for which two (2) or more multi-source drugs with a significant cost difference exist; altering drug reimbursement to AWP minus fourteen (14) percent for generic drugs and AWP minus fifteen (15) percent for brand name drugs; altering the dispensing fee from four (4) dollars and fifty-one (51) cents for all drugs to five (5) dollars for generic drugs and four (4) dollars and fifty (50) cents for brand name drugs; revising the unit dose drug packaging payment to $0.02 per unit dose for a non-unit dose drug re-packaged in unit dose form by a pharmacist; allowing one dispensing fee per rolling twenty-four (24) day period per nursing facility service recipient per drug except for certain circumstances; establishing for an outpatient service recipient, except for a supports for community living service recipient, that a maintenance drug shall be dispensed up to a ninety-two (92) day supply with only one (1) dispensing fee allowed for the maintenance drug refill within the ninety-two (92) day time period; establishing that if the dispensing of an emergency supply of a drug results in partial filling of the quantity or amount

prescribed, that only one dispensing fee shall be allowed for the combined partial fill and subsequent completion fill; and adding gross amount due to drug reimbursement options.

(3) List the type and number of individuals, businesses, organizations, or state and local government affected by this administrative regulation: All Medicaid outpatient pharmacy providers and drug manufacturers will be affected by this administrative regulation.

(4) Provide an assessment of how the above group or groups will be impacted by either the implementation of this administrative regulation, if new, or by the change if it is an amendment: Pharmaceutical providers or manufacturers shall be affected in that drug reimbursement will change to average wholesale price (AWP) minus fourteen (14) percent for generic drugs and AWP minus fifteen (15) percent for brand name drugs; that a state maximum allowable cost may be established for any drug for which two (2) or more multi-source drugs with a significant cost difference exist; in that the dispensing fee is being altered from four (4) dollars and fifty-one (51) cents for all drugs to five (5) dollars for generic drugs and four (4) dollars and fifty (50) cents for brand name drugs; that if the dispensing of an emergency supply of a drug results in partial filling of the quantity or amount prescribed, that only one dispensing fee shall be allowed for the combined partial fill and subsequent completion fill. Long term care pharmaceutical providers will be impacted in that the long term care repackaging fee will be $0.02 per unit dose for a non-unit dose drug re-packaged in unit dose form by a pharmacist. Providers of maintenance drugs to outpatient service recipients will be affected in that a maintenance drug shall be dispensed up to a ninety-two (92) day supply with only one (1) dispensing fee allowed for the maintenance drug refill within the ninety-two (92) day time period. Additionally, this administrative regulation allows one dispensing fee per rolling twenty-four (24) day period per nursing facility service recipient per drug except for certain circumstances and clarifies that over-the-counter drugs dispensed to nursing facility service recipients shall not be reimbursed via the Medicaid outpatient pharmacy program but rather shall be considered part of nursing facility reimbursement.

(5) Provide an estimate of how much it will cost to implement this administrative regulation:
   (a) Initially: DMS estimates that the amendment to this administrative regulation could reduce expenditures as much as $31.5 million annually ($21.98 million federal funds; $9.52 million state funds) for the current fiscal year.
   (b) On a continuing basis: DMS estimates that the amendment to this administrative regulation could reduce expenditures by at least as much as $31.5 million annually ($21.98 million federal funds; $9.52 million state funds) plus additional as yet undetermined amounts depending upon generic drug dispensing/utilization.

(6) What is the source of the funding to be used for the implementation and enforce-

ment of this administrative regulation: Federal funds authorized under the Social Security Act, Title XIX, and matching funds of general fund appropriations and collections will be used to fund the implementation and enforcement of this administrative regulation.

(7) Provide an assessment of whether an increase in fees or funding will be necessary to implement this administrative regulation, if new, or by the change if it is an amendment: Neither an increase in fees nor funding will be necessary to implement this administrative regulation.

(8) State whether or not this administrative regulation establishes any fees or directly or indirectly increases any fees: This administrative regulation neither establishes nor increases any fees.

(9) Tiering: Is tiering applied? (Explain why tiering was or was not used)

Tiering was not appropriate in this administrative regulation because the administrative regulation applies equally to all those individuals or entities regulated by it. Disparate treatment of any person or entity subject to this administrative regulation could raise questions of arbitrary action on the part of the agency. The “equal protection” and “due process” clauses of the Fourteenth Amendment of the U.S. Constitution may be implicated as well as Sections 2 and 3 of the Kentucky Constitution.

FEDERAL MANDATE ANALYSIS COMPARISON

Reg. No. 907 KAR 1:018E Agency Contact: Stuart Owen or Teresa Goodrich (564-6204)

1. Federal statute or regulation constituting the federal mandate.

   Pursuant to 42 USC 1396a et. seq., the Commonwealth of Kentucky has exercised the option to establish a Medicaid Program for indigent Kentuckians. Having elected to offer Medicaid coverage, the state must comply with federal requirements contained in 42 USC 1396 et. seq.

   This administrative regulation complies with federal statutes/regulations governing the Medicaid program and drug reimbursement.

2. State compliance standards.

   This administrative regulation establishes the Department for Medicaid Services reimbursement for drugs in compliance with federal regulations governing drug reimbursement.

3. Minimum or uniform standards contained in the federal mandate.
   This administrative regulation establishes the Department for Medicaid Services reimbursement for drugs in compliance with federal regulations governing drug reimbursement.

4. Will this administrative regulation impose stricter requirements, or additional or different responsibilities or requirements, than those required by the federal mandate?

   This administrative regulation does not impose stricter (than federal) requirements.

5. Justification for the imposition of the stricter standard, or additional or different responsibilities or requirements.

   This administrative regulation does not impose stricter (than federal) requirements.

COMMONWEALTH OF KENTUCKY
CABINET FOR HEALTH AND FAMILY SERVICES
DEPARTMENT FOR MEDICAID SERVICES

907 KAR 1:018E, Reimbursement for Drugs

Summary of Material Incorporated by Reference

The "MAC Price Inquiries and Research Request Form, December 2004 edition" is a one (1) page form utilized by providers to appeal a state maximum allowable cost price for a drug.